UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,919	02/04/2004	Joseph K. Belanoff	019904-002610US	5231

20350 7590 01/25/2010

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
01/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/772,919
Filing Date: February 04, 2004
Appellant(s): BELANOFF, JOSEPH K.

Carol P. Johns
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 28, 2009 appealing from the Office action mailed May 19, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,150,349	Schatzberg et al.	11-2000
6,362,173	Schatzberg et al.	3-2002
6,011,025	Gebhard	1-2000

Belanoff et al. "Mifepristone Treatment for Psychotic Depression" Current Psychiatry Reports, Vol. 4 No. 3, June 2002 page 164.

Stowe et al., "Women at risk for postpartum-onset major depression" Am J Obstet. Gynecol. Vol. 173, No. 2, August 1995 , pages 639-645.

Bradley P. Morgan et al. "Discovery of Potent, Nonsteroidal, and Highly Selective Glucocorticoid Receptor Antagonists" J Med. Chem. 2002, 45 pages 2417-2424.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, "wherein the glucocorticoid receptor antagonist comprises a steroidal skeleton with at least one phenyl-containing moiety in the 11β position of the steroidal skeleton" (present in claim 3) and "wherein the phenyl-containing **moiety** in the 11β position of the steroidal skeleton is a dimethylaminophenyl **moiety**" (present in claim 4) is a concept that was not present in the specification as originally filed. Applicants are advised that the issue here is (1) what is meant by a "steroidal skeleton" and (2) what is meant by a "phenyl-containing moiety" and a "dimethylaminophenyl moiety". There do not appear to be any examples or drawings of a steroidal skeleton to show what is included or excluded from this structure. Further, the IUPAC definition of a moiety is "a half of a molecule including substructures of functional groups". It is unclear to the examiner if there is another part of the moiety that is undisclosed or if the other half of the moiety is the "steroidal skeleton".

The specification as originally filed contains the following disclosures concerning steroidal skeletons:

"in one aspect of the invention, the glucocorticoid receptor antagonist comprises a steroidal skeleton with at least one phenyl containing moiety in the 11-13 position of the steroidal skeleton. In one aspect, the phenyl-containing moiety in the 11-13

position of the steroidal skeleton is a dimethylaminophenyl moiety". (page 2 paragraph [0009]).

The above disclosure, however, does not provide adequate support by such descriptive means as words, structures, figures, diagrams and formula that fully set forth the glucocorticoid receptor antagonist comprising a steroidal skeleton with at least one phenyl-containing moiety in the 11β position of the steroidal skeleton" (present in claim 3) and "the phenyl-containing moiety in the 11β position of the steroidal skeleton is a dimethylaminophenyl moiety" (present in claim 4).

Written Description

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in her opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at § 2163 - 2163.05. In particular, while Applicant's specification as originally filed does not contain an example of what is meant by a "steroidal skeleton" or regarding the "moieties of "phenyl containing" and . "dimethylaminophenyl moiety" what other elements are included or excluded by the terms recited above. "A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir.

1996)"(emphasis added), see MPEP § 2163(I)(A). Also, "See also *In re Smith*. 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ('Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.' (emphasis added)).", see MPEP § 2163.05(II).

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of a "steroidal skeleton" with at least one "phenyl containing moiety" in the 11-13 position of the steroidal skeleton and the phenyl-containing moiety in the 11-13 position of the steroidal skeleton is a "dimethylaminophenyl moiety".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being obvious over Schatzberg et al. U.S. Patent No. 6,150,349.

Schatzberg et al. teach glucocorticoid receptor antagonists (GR antagonist) (see abstract), specifically, those GR antagonists can comprise a steroidal skeleton with at least one phenyl (e.g. dimethylaminophenyl) containing moiety in the 11 β position of the steroidal skeleton, for example, RU 486, RU009 and RU044, for the treatment of psychosis in a patient in need thereof (column 3, lines 56-64). Further, Schatzberg et al. teach a condition or illness involving psychosis can be classified as a psychotic disorder not otherwise specified. According to DSM IV criteria, this category includes psychotic symptomology (i.e. delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behavior) about which there is inadequate information to make a specific diagnosis or about which there is contradictory information, or disorders with psychotic symptoms that do not meet the criteria for any specific psychotic disorder. Examples include**: postpartum psychosis** that does not meet other DSM IV categories; psychotic symptoms that have lasted for less than one month but have not yet remitted; persistent auditory hallucinations in the absence of other features;

persistent nonbizarre delusions with period of overlapping mood episodes that have been present for a substantial portion of the delusional disturbance; and, situations in which the clinician has concluded that a psychotic disorder is present but is unable to determine whether it is primary, due to general medical condition or is substance-induced (column 15, lines 46-64).

It would have been obvious to employ the recited GR antagonists for amelioration of the symptoms of postpartum psychosis motivated by the teaching of Schatzberg et al. who teach that GR antagonists ameliorate psychosis and according to Schatzberg et al. the DSM IV includes postpartum psychosis in its categorization of the symptomology of psychosis in general.

Schatzberg et al. teach daily administration orally and transdermally (column 18, lines 16-29).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberg et al. as applied to claims 1-11 above, and further in view of Belanoff et al. (U)

Schatzberg et al. teach glucocorticoid receptor antagonists (GR antagonist), specifically, mifepristone (RU 486) (see abstract) for the treatment of psychosis in a patient in need thereof (see, for example, claim 1). Further, Schatzberg et al. teach a condition or illness involving psychosis can be classified as a psychotic disorder not otherwise specified. According to DSM IV criteria, this category includes psychotic symptomology (i.e. delusions, hallucinations, disorganized speech, grossly disorganized

or catatonic behavior) about which there is inadequate information to make a specific diagnosis or about which there is contradictory information, or disorders with psychotic symptoms that do not meet the criteria for any specific psychotic disorder. Examples include**: postpartum psychosis** that does not meet other DSM IV categories; psychotic symptoms that have lasted for less than one month but have not yet remitted; persistent auditory hallucinations in the absence of other features; persistent nonbizarre delusions with period of overlapping mood episodes that have been present for a substantial portion of the delusional disturbance; and, situations in which the clinician has concluded that a psychotic disorder is present but is unable to determine whether it is primary, due to general medical condition or is substance-induced (column 15, lines 46-64).

Schatzberg et al. does not teach the GR antagonist is a "specific" GR antagonist.

Belanoff et al. teach that mifepristone is a specific GR antagonist (see page 164, column 2).

It would have been made obvious to one of ordinary skill in art at the time it was made to employ a specific GR antagonist for amelioration of the symptoms of postpartum psychosis motivated by the teaching of Schatzberg et al. who teach that GR antagonists ameliorate psychosis and according to Schatzberg et al. the DSM IV includes postpartum psychosis in its categorization of the symptomology of psychosis in general an further in view of Belanoff et al. who teach mifepristone is a specific GR antagonist.

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being obvious over Schatzberg et al. U.S. Patent No. 6,362,173.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Schatzberg et al. teach glucocorticoid receptor antagonists (GR antagonist) (see abstract), specifically, those GR antagonists can comprise a steroidal skeleton with at least one phenyl (e.g. dimethylaminophenyl) containing moiety in the 11 β position of the steroidal skeleton, for example, RU 486, RU009 and RU044, for the treatment of psychosis in a patient in need thereof (column 1, lines 25-37). Further, Schatzberg et al. teach a condition or illness involving psychosis can be classified as a psychotic

disorder not otherwise specified. According to DSM IV criteria, this category includes psychotic symptomology (i.e. delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behavior) about which there is inadequate information to make a specific diagnosis or about which there is contradictory information, or disorders with psychotic symptoms that do not meet the criteria for any specific psychotic disorder. Examples include**: postpartum psychosis** that does not meet other DSM IV categories; psychotic symptoms that have lasted for less than one month but have not yet remitted; persistent auditory hallucinations in the absence of other features; persistent nonbizarre delusions with period of overlapping mood episodes that have been present for a substantial portion of the delusional disturbance; and, situations in which the clinician has concluded that a psychotic disorder is present but is unable to determine whether it is primary, due to general medical condition or is substance-induced (column 15, lines 36-54).

It would have been obvious to employ the recited GR antagonists for amelioration of the symptoms of postpartum psychosis motivated by the teaching of Schatzberg et al. who teach that GR antagonists ameliorate psychosis and according to Schatzberg et al. the DSM IV includes postpartum psychosis in its categorization of the symptomology of psychosis in general.

Schatzberg et al. teach daily administration orally and transdermally (column 18, lines 5-18).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberg et al. as applied to claims 1-11 above, and further in view of Belanoff et al. (U).

Schatzberg et al. teach glucocorticoid receptor antagonists (GR antagonist), specifically, mifepristone (RU 486) (column 1, lines 25-37)) for the treatment of psychosis in a patient in need thereof (see, for example, claim 1). Further, Schatzberg et al. teach a condition or illness involving psychosis can be classified as a psychotic disorder not otherwise specified. According to DSM IV criteria, this category includes psychotic symptomology (i.e. delusions, hallucinations, disorganized speech, grossly disorganized or catatonic behavior) about which there is inadequate information to make a specific diagnosis or about which there is contradictory information, or disorders with psychotic symptoms that do not meet the criteria for any specific psychotic disorder. Examples include: **postpartum psychosis** that does not meet other DSM IV categories; psychotic symptoms that have lasted for less than one month but have not yet remitted; persistent auditory hallucinations in the absence of other features; persistent nonbizarre delusions with period of overlapping mood episodes that have been present for a substantial portion of the delusional disturbance; and, situations in which the clinician has concluded that a psychotic disorder is present but is unable to determine whether it is primary, due to general medical condition or is substance-induced (column 15, lines 46-64).

Schatzberg et al. does not teach the GR antagonist is a "specific" GR antagonist.

Belanoff et al. teach that mifepristone is a specific GR antagonist (see page 164, column 2).

It would have been made obvious to one of ordinary skill in art at the time it was made to employ a specific GR antagonist for amelioration of the symptoms of postpartum psychosis motivated by the teaching of Schatzberg et al. who teach that GR antagonists ameliorate psychosis and according to Schatzberg et al. the DSM IV includes postpartum psychosis in its categorization of the symptomology of psychosis in general an further in view of Belanoff et al. who teach mifepristone is a specific GR antagonist.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberg et al U.S. Patent No. 6,150,349, in view of Stowe et al, and in view of Bradley P. Morgan et al, (PTO-892 dated 9/20/2007, J. Med. Chem. 45, 2417-2424 (2002)).

Schatzberg et al. and Stowe et al. do not teach the specific glucocorticoid receptor antagonists listed in claim 7.

Bradley P. Morgan et al, J. Med. Chem. 45, 2417-2424 (2002) teach GR antagonist compounds (see title, abstract, and pg 2417 first full paragraph) 4α(S)-Benzyl-2(R)-prop-l-ynyl- 1,2,3,4,4α,9,10,10α(R)-octahydro-phenanthrene-2,7-diol diol (pg 2421 3rd full paragraph)and 4α(S)-Benzyl-2(R)- chloroethynyl-1,2,3,4,4α,9,10,10α(R)-octahydro-phenanthrene-2,7-diol (pg 2421 2nd full paragraph).

Someone of ordinary skill in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties, and which would have an obvious reasonable expectation of success.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberg, et al U.S. Patent No. 6,150,349, in view of Stowe et al, in view of Gebhard (PTO-892 dated 9/20/2007, US 6,011,025).

Schatzberg et al and Stowe et al do not teach when the specific glucocorticoid receptor antagonists listed in claim 8.

Gebhard claims the glucocorticoid receptor antagonist (11β,17β)- 11-(1,3-benzodioxol-5-yl)-17-hydroxy-17-(1 -propynyl)estra-4,9-dien-3-one (see abstract and claim 6).

Therefore, one having ordinary skill in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties and would have a reasonable expectation of success.

(10) Response to Argument

Appellant asserts that postpartum psychosis (PPP) is not included among those amenable to treatment with a GRA (glucocorticoid receptor antagonist). Appellants assert that rebuttal evidence has been submitted teaching away from treating a postpartum mother with a GRA, because glucocorticoid levels fall dramatically after birth (childbirth). In response, as part of the SUMMARY OF THE INVENTION (column 3, line

45), Schatzberg et al. ('349) teach treatment with glucocorticoid receptor antagonists for amelioration of psychosis. Schatzberg et al further teach in the "Detailed Description of the Invention" the scope of what is encompassed as treatable which scope includes "postpartum psychosis" (column 15, line 55). Regarding the evidence drawn to the dramatic fall of glucocorticoid levels after birth, the evidence is drawn to levels immediately after childbirth while the instant claims are drawn to treatment of PPP that arise within 9 months of childbirth. The levels of glucocorticoid immediately after birth are not probative of the instant method and it's obviousness. Appellant states Schatzberg et al. does not teach that all psychotic symptoms are treatable with a GRA, only those associated with glucocorticoid regulatory dysfunction. In response, as stated supra, Schatzberg et al. teach methods of treating psychosis associated with glucocorticoid related dysfunction by administration of an amount of a glucocorticoid receptor antagonist effective to ameliorate the psychosis (Summary of the Invention, column 3, lines 45-50) and further disclose in the "Detailed Description of the Invention" that a condition involving psychosis (such as those psychoses treated with GRA's supra) include postpartum psychosis (column 15, line 55). Appellant states that "a fair reading would not lead a reader to conclude that Schatzberg teaches the use of GRAs for treating any and all forms of psychosis". In response, the Appellant is correct. One would only include those that are listed in the "detailed description of the invention", which includes postpartum psychosis. The MPEP states "A detailed description of the invention and drawings follows the general statement of invention and brief description of the drawings. This detailed description, required by **37 CFR 1.71**, **MPEP § 608.01**,

must be in such particularity as to enable any person skilled in the pertinent art or science to make and use the invention without involving extensive experimentation." If this disclosure in column 15 drawn to postpartum psychosis is only "for informational purposes only", then the information would be listed in the "background of the invention" see MPEP §608.01(c). However, as stated supra, the citation drawn to postpartum psychosis is clearly in the "detailed description of the invention" and encompassed as a treatable condition. Appellant states that the Examiner has not provided evidence that a GRA could be used to treat every psychotic syndrome or PPP in particular. Clearly, Schatzberg et al. is all the evidence that is required. Regarding the declaration under 37 CFR 1.132, it is insufficient because it refer(s) only to the ineffectiveness of mifepristone for schizoaffective disorders, however, it does not address individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. In essence the declaration confirms with is disclosed in the Schatzberg et al. reference, i.e. "schizophrenia and manic states are not within the scope of the definition of psychosis and thus are not treated by the methods of the invention" (column 7, lines 8-11). The significance of the Exhibits drawn to distinguishing postpartum psychosis and postpartum psychiatric disorders i.e. from postpartum depression is unclear. Appellant states that there is nothing in any of these articles suggesting that PPP was known to be associated with glucocorticoid regulatory dysfunction. In response, this argument is not germane to the rejections stated supra. Appellant states that "the focus of the [Schatzberg et al.] application is on major depression and the claims are limited to

method of treating psychosis associated with major depression. In response, Schatzberg et al. is drawn to treatment of individuals with **psychosis** i.e., "schizophrenia and manic states are caused by abnormal nerve structure, i.e., a "hardwiring" problem. In contrast, it is believed that the pathophysiology of psychosis is related to neurochemical problems, particularly, HPA axis regulatory dysfunction (this theory is extended by the instant invention, in which it was discovered that the agents which inhibit the **binding of cortisol** to its receptor will **treat psychosis**)." (column 7, lines 1-9). Appellant states that column 16 of the Schatzberg et al. reference describes schizophrenia with is excluded from the invention. Since Appellant did not specifically recite a line, it can only be assumed that Appellant was referring to the statement that "the psychotic component of schizoaffective disorders is ameliorated by the methods of this invention" (column 16, lines 46-47) which is in accord with the passage from column 7, lines 1-9, repeated supra. With regard to the evidence submitted (Ex. F Elendov et al.), the evidence is drawn to an explanation that cortisol as well as other hormones, increases in late pregnancy and falls rapidly in the early postpartum period. In response to Appellant's argument that the reference teaches away from the instant invention, it is noted that the features upon which applicant relies (i.e., cortisol levels of the immediate postpartum/ante partum period) are not recited in the rejected claim(s). The instant claims are drawn to treatment within 9 months of childbirth. Ex. G is drawn to similar evidence ("cortisol levels fall abruptly at delivery") hence the Examiner is drawn to the same conclusion; the features that are relied on are not recited in the rejected claims.

Appellant states that the secondary references do not cure the deficiencies in the Examiner's arguments based on Schatzberg [et al.].

Appellant states that there is no explanation of what Stowe teaches or why it is cited. As stated in the response dated May 19, 2009 and the office action dated May 28, 2008, Stowe is employed to show the postpartum patient population may include those without predisposed depression tendencies. Appellant states that Stowe also fails to link glucocorticoid regulatory dysfunction to PPP. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Bradley teaches the specific glucocorticoid receptor antagonists recited in instant claim 7 and Schatzberg et al. teach the method of using GRA's to treat psychosis, including postpartum psychosis as stated supra. Appellant states that "Bradley and Gebhard teach particular GRA compounds and do not cure the defects in the Examiner's arguments based on Schatzberg." Further Appellant persists in stating that "nothing in Schatzberg, or Belanoff, or any other source cited by the Examiner suggests that PPP is associated with glucocorticoid regulatory dysfunction".

With regard to claims 3 and 4 rejected under 35 USC §112, first paragraph as lacking written description, Appellant states that "the GRA compounds are disclosed in the specification, and claims 3 and 4 are described using an internationally recognized standardized naming system, namely IUPAC nomenclature." Appellant states that the

GRAs recited in claims 3 and 4 represent a known class of compounds as evidenced the references cited in the specification that describe GRAs. Appellant further indicates that the activity of a given compound as a GRA can be tested as described in the section entitled "Identifying Specific Glucocorticoid Receptor Antagonists" (page 14). In response, the paragraphs cited by Appellant do not teach a written description of the invention, and of the manner and process of making and using it, in such **full, clear, concise, and exact terms** as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. Appellant describes what is contained in the instant specification, however, does not address the ambiguities of the claim, which include:

A) the description of the "steroidal skeleton"

B) what is meant by "at least one"

C) what is a "phenyl containing moiety"

D) what is a "dimethylaminophenyl moiety"

Appellant further quibbles about how the word moiety was described in an previous office action. For the record, the word "moiety" is defined by IUPAC as "part of a molecule" not "half a molecule" as Appellant indicates. The real question that Appellant leaves unanswered is what is the other part of the moiety? Further Appellant states that the nomenclature of steroids do not require any further description because of the evidence termed Ex. I. In response, in steroids, where minor changes in structure, including the addition, deletion and/or substitution of single groups frequently alters the biological activity of a steroid. Accordingly, essentially identical structures are

generally required before one skilled in the art would be inclined to believe that two steroids possess the same biological properties or characteristics. *Ortho Pharmaceutical Corp. v. Smith*, 22 USPQ2d 1119, 1125 (Fed. Cir. 1992). Appellant further argues that "the Examiner also seems to apply the standard of enablement by stating that it would require undue, unpredictable experimentation to practice the claimed invention". In response, the Examiner cannot find these words in the rejection. The rejection clearly states that "Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement".

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Donna Jagoe /Donna Jagoe /

Conferees:

/YVONNE L. EYLER/

Supervisory Patent Examiner, Art Unit 1619

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612